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Proposed Registration Decision PRD2013-18

Garlic Juice

(publié aussi en français)

19 August 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2013-18E (print version)
H113-9/2013-18E-PDF (PDF version)

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Overview

Proposed Registration Decision for Garlic Juice

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of U C Garlic Juice (technical grade active ingredient) and Mosquito Barrier (end-use product), containing the technical grade active ingredient garlic juice, to repel mosquitoes in outdoor environments.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of U C Garlic Juice and Mosquito Barrier.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on garlic juice, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on garlic juice, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Garlic Juice?

Garlic juice is an extract of garlic (*Allium sativum* var. *sativum*). It is the active ingredient in the end-use product Mosquito Barrier. Various diallyl sulfide compounds, which are among the main components of garlic juice, are repellent to mosquitoes.

Health Considerations

Can Approved Uses of Garlic Juice Affect Human Health?

Garlic juice is unlikely to affect your health when used according to label directions.

Exposure to garlic juice may occur when handling and applying the product, Mosquito Barrier, as well as during typical residential activities following application. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, garlic juice, is of low acute toxicity by the oral and dermal routes, may be a skin and eye irritant, and a possible dermal sensitizer. Because garlic is a known mucosal irritant, inhalation of garlic juice mist or vapour may result in throat and respiratory tract irritation. The end-use product, Mosquito Barrier, is of low acute toxicity by both the oral and dermal route, may be a skin and eye irritant, and a possible dermal sensitizer. Cautionary statements alerting the user to garlic juice's acute toxicity, potential as a skin and eye irritatant, and dermal sensitizer are required on the technical grade active ingredient product label, as well as Mosquito Barrier being a possible skin and eye irritant, and a dermal sensitizer.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Inhalation, dermal, and ocular exposures are possible when applying the product, particularly to the applicator and bystanders located near the treatment area. Also, entry into a recently sprayed area may result in dermal exposure. Therefore, spray advisory and restricted entry statements are required on the end-use product label to minimize applicator and bystander exposures.

The data requirements for short-term toxicity, prenatal developmental toxicity, and genotoxicity were not required by the PMRA based on the long history of safe consumption of garlic as a whole foodstuff and garlic juice in natural health products.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The proposed use pattern of Mosquito Barrier is for non-food situations. Garlic readily degrades in the environment, so any inadvertent exposure of garlic juice to food, feed, or water from drift or direct contact is not expected to result in any dietary risk.

Occupational Risks From Handling Garlic Juice

Occupational Risks are not of concern when garlic juice is used according to label directions, which include protective measures.

Domestic users mixing, handling and applying Mosquito Barrier to areas that attract mosquitoes, such as plants, shrubs, turf, and under decks and porches, can come in direct contact with garlic juice on the skin and in the eyes. Following the precautionary label statements aimed at minimizing exposure to the product will ensure domestic users are appropriately protected. Potential for inhalation of garlic juice while handling and applying the product is anticipated to be negligible if users observe the precautionary label statements.

Accidental bystander exposure is possible from spray drift, but exposure is expected to be negligible if the precautionary label statements are observed by the applicator.

Post-application exposure is possible in individuals who immediately enter freshly treated areas. The transfer of garlic juice from turf or foliar application to an individual who is not sensitive to garlic will not pose a health concern.

Value Considerations

What Is the Value of Mosquito Barrier?

Mosquito Barrier is an area repellent that can reduce nuisance levels of mosquitoes.

Diluted in water to a concentration of 3–6%, Mosquito Barrier is applied as a broadcast spray to vegetation and other substrates to repel mosquitoes from the area.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Mosquito Barrier to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The statements, "MAY BE A SKIN AND EYE IRRITANT" and "POTENTIAL SKIN SENSITIZER" have been included on the principal display panel of the general label and "Do not swallow", "Avoid getting on skin and in eyes", "May cause skin and eye irritation", "Avoid inhaling/breathing mist or vapours", and "Potential skin sensitizer" have been included in the PRECAUTIONS section of the secondary display panel of the end-use product label.

Because some individuals may be sensitive to garlic the statements, "Apply only when the potential for drift is minimal", "Individuals who are sensitive or allergic to garlic should avoid handling Mosquito Barrier" and "Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or until after a heavy rain" have also been included in the PRECAUTIONS section of the secondary display panel of the general label.

Next Steps

Before making a final registration decision on garlic juice, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the PMRA's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on garlic juice (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Garlic Juice

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Garlic juice
Function	Insecticide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	Not applicable
2. **Chemical Abstracts Service (CAS)**	Not applicable
CAS number	Not applicable
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	99.3%

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—U C Garlic Juice

Property	Result
Colour and physical state	Yellowish sand liquid
Odour	Strong garlic odour
Melting range	N/A
Boiling point or range	Not required
Density	1.03–1.1 g/mL
Vapour pressure at 20°C	Not required
Ultraviolet (UV)-visible spectrum	N/A

Solubility in water at 20°C	Slightly soluble
Solubility in organic solvents at 20°C (g/100 mL)	Not required
n-Octanol-water partition coefficient (K_{OW})	N/A
Dissociation constant (pK_a)	N/A
Stability (temperature, metal)	The chemical composition of the product changes over time as the chemical compounds formed during manufacturing process undergo additional reactions.

End-Use Product—Mosquito Barrier

Property	Result
Colour	Yellowish sand
Odour	Strong garlic odour
Physical state	Liquid
Formulation type	Liquid
Guarantee	99.3%
Container material and description	Plastic, 946 mL
Density	1.03–1.1 g/mL
pH	3.43
Oxidizing or reducing action	Not required
Storage stability	Product is stable at 20°C for 36 months minimum.
Corrosion characteristics	Non-corrosive to the packaging material.
Explodability	The product is not potentially explosive.

1.3 Directions for Use

Mix Mosquito Barrier in water at the rate of 30 mL/L. To aid mixing and spreading of the spray solution, up to 10 mL of mild liquid soap (do not use detergent) per litre of water may be added. If a sticker is desired to aid retention of the product on plants, up to 20 mL of vegetable oil (canola or corn oil; do not use soybean or peanut oil) with up to 10 mL of mild liquid soap per litre of water may be added. No danger to plants is expected if label directions are followed, but test on a small area if in doubt about the sensitivity of a particular plant.

Use in areas that attract mosquitoes such as grass, plants, shrubs and under decks and porches. Re-apply after heavy rain or if mosquitoes continue to be a problem.

1.4 Mode of Action

The mode of action of garlic juice has not been well characterized. However, diallyl sulfides from garlic oil (which are among the main components in garlic juice) have been demonstrated to produce electrophysiological responses in mosquito antennae and to provide significant repellency to mosquitoes when applied to human skin (Campbell 2009).

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

Not required for garlic juice.

2.2 Method for Formulation Analysis

Not required for this product.

2.3 Methods for Residue Analysis

Not required for this product.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of data available in the literature on the toxicology of garlic juice was conducted by the PMRA. The scientific quality of the data is acceptable and the database is sufficiently complete to define the majority of the toxic effects that may result from exposure to garlic juice when it is applied as a pest control product.

Acute toxicity information has been previously reviewed for garlic powder including the diallyl disulfide and diallyl sulfide. Of note garlic oil contains up to 15 % more allicin derivatives than garlic juice therefore, the toxicity of garlic juice is expected to be reduced relative to that of garlic oil. The information summarized in Table 1 (see Appendix 1) was used to assess the toxicological effect of the technical grade active ingredient (TGAI), U C Garlic Juice, and the end-use product (EP), Mosquito Barrier. The TGAI and EP contain no formulants of toxicological concern.

Garlic juice is expected to be of low acute toxicity by the oral route based on the toxicity of garlic oil. Based on the acute dermal toxicity of both diallyl sulfide and diallyl disulfide in rats, garlic juice is expected to be of low acute toxicity by the dermal route. Garlic juice, a mucosal irritant, will result in irritation when inhaled. Mosquito Barrier is expected to be of low acute toxicity by both the oral and dermal routes.

Diallyl disulfide is moderately irritating to the eyes of rabbits and both diallyl sulfide and diallyl disulfide are severely irritating to the skin of rabbits. Published case studies on the dermal effects of garlic in humans (skin ulcerations, severe erythema, and edema) reflect the findings for dermal irritation of the diallyl sulfide compounds. Based on these findings, garlic juice may be a skin irritant and eye irritant. Diallyl disulfide and by extension, garlic juice, may also be a dermal sensitizer in guinea pigs. Therefore, it is expected that Mosquito Barrier may be a skin and eye irritant, as well as a possible dermal sensitizer.

The mutagenicity of garlic has been reported in bacteria, but, based on the long history of safe consumption of garlic and the low potential for exposure of individuals to Mosquito Barrier, short-term toxicity, prenatal developmental toxicity, and genotoxicity data requirements for garlic juice were not required by the PMRA.

3.2 Food Residue Exposure Assessment

A food residue exposure assessment was not required for the non-food/feed uses of Mosquito Barrier.

3.3 Residential Risk Assessment

3.3.1 Use Description/Use Scenario

The proposed domestic use of Mosquito Barrier is as an area insect repellent spray after dilution of 30 mL to 60 mL of Mosquito Barrier per litre of solution. Exposure was based on a daily maximum rate of application of a 1 L bottle of diluted Mosquito Barrier and incidental contact with treated objects and areas, such as foliage and turf. The applicator will handle a maximum of 30 to 60 mL a.i. per day and the number of applications per year is unlimited. According to the product label, the higher application rate is only recommended if mosquitoes are already present.

3.3.2 Applicator Exposure and Risk Assessment

Exposure to Mosquito Barrier is expected to be short-term in duration and predominantly by the inhalation and dermal routes. Accidental ingestion and ocular exposure of the end-use product are also possible during application, but are likely to only be minor routes of exposure. Although a margin of exposure could not be estimated based on the toxicological information available, exposure to the end-use product, when label instructions and precautions are observed, is not expected to pose a health concern.

The risk due to dermal and inhalation exposure of the applicator to garlic juice is anticipated to be negligible if the precautionary label statements are observed. Individuals with garlic sensitivities should not handle Mosquito Barrier at all.

Bystander Exposure and Risk Assessment

Bystanders are likely to walk in and out of a treated area. This transient exposure is not expected to pose a health risk for individuals who are not sensitive to garlic. Individuals who are sensitive to garlic should avoid treated areas until dry or until after a heavy rainfall.

Accidental bystander exposure is possible from spray drift, the extent to which may be limited with appropriate label statements warning against application on days where the wind is sufficient to cause drift.

These mitigative measures are expected to minimize the potential for exposure of bystanders to Mosquito Barrier when applied in outdoor domestic settings.

3.3.3 Post-Application Exposure

Post-application activities are expected to be typical of a residential setting, thus post-application exposure to adults, and children is likely. Individuals with sensitivities to garlic should avoid recently treated areas until dry or until after a heavy rain.

4.0 Summary

4.1 Human Health and Safety

The available toxicological information on garlic is adequate to identify the majority of toxic effects that may result from human and companion animal exposure to the active ingredient. Eye and skin irritation, and dermal sensitization were observed in laboratory animals. No other toxicologically significant effects were reported in available information on garlic juice.

The precautionary statements on the product labels are adequate to protect applicators and bystanders. The product label will instruct domestic users not to apply Mosquito Barrier if the wind is sufficient to cause drifting of the spray away from treated areas. Judicious application of the product is not expected to result in applicators being exposed to concentrations of garlic juice that would be of concern. Furthermore, allowing Mosquito Barrier to dry after each application will ensure that bystanders and pets are unlikely to come in contact with garlic juice at concentrations that would be of concern.

Because Mosquito Barrier is not to be applied to food or feed, the establishment of a maximum residue limit was not required for garlic juice.

Individuals who are sensitive (i.e., allergic) to garlic are advised to avoid handling Mosquito Barrier, as well entering recently treated areas.

5.0 Value

5.1 Effectiveness Against Pests

Use history information was provided by six different individuals collectively having experience using the product in Manitoba, Ontario, Nova Scotia, and Prince Edward Island. All individuals stated that expectations were met (most indicating that mosquitoes were all but eliminated from the treated area), although in one case only "moderately" (estimated 50% reduction in numbers of mosquitoes). Most individuals emphasized that no adverse effects on the vegetation were observed and that there are very few comparable alternatives available for use. Mosquito Barrier has value in reducing nuisance levels of mosquitoes, especially in situations where the use of conventional insecticides may be undesirable. Examples of situations where Mosquito Barrier might be of particular value include outdoor weddings and public events in community parks.

5.2 Sustainability

5.2.1 Survey of Alternatives

Alternative pest control products registered for domestic use to manage mosquitoes in outdoor settings include area repellents containing garlic oil, mosquito coils and heated lanterns containing allethrins.

5.2.2 Compatibility with Current Management Practices Including Integrated Pest Management

Mosquito Barrier is compatible with other methods used to manage mosquitoes.

5.2.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Because the mode of action of Mosquito Barrier is as an insect repellent, rather than an insecticide, it is not expected to exert selection pressure that would lead to the development of resistance.

6.0 Summary

6.1 Value

Mosquito Barrier has value as an area repellent to reduce nuisance levels of mosquitoes.

7.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of U C Garlic Juice and Mosquito Barrier, containing the technical grade active ingredient garlic juice, to repel mosquitoes in outdoor environments.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

List of Abbreviations

Acronym	Definition
a.i.	active ingredient
ACGIH	American Conference of Governmental Industrial Hygienists
bw	body weight
cm	centimetre(s)
EP	end-use product
g	gram
IUPAC	International Union of Pure and Applied Chemistry
L	litre
LD_{50}	lethal dose 50%
mL	millilitre(s)
PMRA	Pest Management Regulatory Agency
ppm	parts per million
TGAI	technical grade of the active ingredient
TLV	Threshold Limit Value
TWA	Time Weighted Average
UV	Ultra Violet

Appendix I Tables and Figures

Table 1 Acute Toxicity of Garlic Juice and Its Associated End-use Product (Mosquito Barrier)

Study Type	Species	Result	Comment	Reference
Acute Toxicity of garlic juice (technical): The measured concentrations of diallyl disulfide are 40 to 50% in garlic juice and 45 to 65% in garlic oil. Garlic oil therefore contains up to 15% more diallyl disulfide than garlic juice. Acute Toxicity below are for Garlic Oil, diallyl disulfide and diallyl sulfide.				
Oral	Rat	Garlic Oil LD_{50} 30 g/kg bw	Low toxicity	1861165
Dermal	Rat	Diallyl sulfide LD_{50} > 5 g/kg bw Diallyl disulfide LD_{50} (♂) 1826 mg/kg bw	Low toxicity	1860536 1860541
Inhalation	The data requirement was waived on the basis of available information which did not note any deaths or significant acute effects, other than mucosal irritation and lacrimation, from the inhalation of garlic oil vapour. The ACGIH has listed a TLV–TWA of 0.5 ppm (0.03 mg/L) for diallyl disulfide, a major component of Garlic Oil, based on the irritation and lacrimation properties of the compound.			1864853
Skin irritation	Rabbit	Diallyl sulfide Irritation and skin ulceration (occluded patch test for 24 hours) Diallyl disulfide Severe erythema (1 hour after exposure)	Severe irritation	1860488 1860536 1860541
Eye irritation	Rabbit	Diallyl disulfide Corneal opacity and conjunctivitis resolved by day 14 of study	Moderate irritation	1860488
Skin sensitization	Guinea Pig	Diallyl disulfide Positive for dermal sensitization	Dermal sensitization	1860536
Acute Toxicity of End-Use Product – Mosquito Barrier				
Oral	Refer to the acute toxicity of garlic oil			
Dermal	Refer to the acute toxicity of garlic oil			
Inhalation	Refer to the acute toxicity of garlic oil.			
Skin irritation	Based on available information, the end-use product may be a skin irritant.			
Eye irritation	Based on available information, the end-use product may be an eye irritant.			
Skin sensitization	Based on available information, the end-use product is a possible skin sensitizer.			

References

A. List of Studies/Information Submitted by Registrant

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2189476 Detailed Production Process, DACO: 2.11.3 CBI
2189480 2007, Certificate of Analysis, DACO: 2.16 CBI

2.0 Human and Animal Health

2189477 Use Description/Scenario, DACO: 5.2

3.0 Value

2275301 2012, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275302 2012, Benefit Information and Use History, DACO: 10.2.3.3(C)
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2275305 2012, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275307 2013, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275309 2007, Certificate of Analysis, DACO: 10.2.1
2275310 Campbell, C.J., 2009, Analyses of essential and edible oils, and constituents therein, as candidate repellents for the yellow fever mosquito Aedes aegypti L. (Diptera: Culicidae), M.P.M. thesis, Simon Fraser University, Burnaby, British Columbia, DACO: 10.2.1
2275312 2012, Benefit Information and Use History, DACO: 10.2.3.3(C)
2275315 2013, Scientific Rationale Summary, DACO: 10.2.3.1

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1.0 Human and Animal Health

1859677 Chapter 8 Garlic Forensic Science and Medicine. Herbal Products: Toxicology and Clinical Pharmacology, Second Edition., DACO: 4.8
1860488 RTECS Registry of Toxic Effects of Chemical Substances Allyl disulfide, Canadian Centre for Occupational Health & Safety, DACO: 4.2.1,4.2.2,4.2.4,4.2.5,4.3.1,4.5.4,4.5.5
1860536 Fragrance raw materials monographs DIALLYL DISULPHIDE, DACO: 4.2.1,4.2.2,4.2.5,4.2.6,4.5.4,4.5.5
1860541 Fragrance raw materials monographs DIALLYL SULPHIDE, DACO: 4.2.1,4.2.2,4.2.5,4.2.6,4.5.4,4.5.5
1861150 2003, Rules and Regulation Diallyl Sulfides; Exemption from the Requirement of a Tolerance, Federal Register Vol. 68, No. 131, DACO: 4.8
1861165 RTECS Registry of Toxic Effects of Chemical Substances - Garlic Oil, Canadian Centre for Occupational Health and Safety, DACO: 4.2.1,4.3.1

1861167 ChemIDplus Advanced Allyl sulfide, United States National Library of Medicine, DACO: 4.2.1

1861180 garlic oil china 8000-78-0 allium sativum l. bulb oil, DACO: 4.8

1861197 ChemIDplus Advanced Allyl sulfide, U.S. National Library of Medicine, DACO: 4.2.1,4.2.2

1861206 ChemIDplus Advanced Diallyl disulfide, U.S. National Library of Medicine, DACO: 4.2.1,4.2.2

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